

In the Claims:

Please cancel claims 30 and 35 without prejudice or disclaimer of the subject matter thereof.

Remarks

The specification has been amended to correct the date of deposit of ATCC Deposit No. 75899 from that of September 28, 1994 to that of September 29, 1994. Support for this amendment can be found in the ATCC-deposit receipt form for ATCC Deposit No. 75899 filed herewith as Attachment A to the accompanying Declaration of John M. Greene and Robert D. Fleischmann under 37 C.F.R. § 1.132.

Claims 30 and 35 have been canceled. Thus, claims 21-29 and 31-34 are active in the application. Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Consideration of References Cited in the Information Disclosure Statement filed April 18, 1997

At page 1, item 4, of Paper No. 17, the Examiner states that certain references (AR7, AS7, AS8, AT8, AR9, AS2 [sic: AS9], AR10, AS10, AT10, and AR11) were considered but struck from the Form 1449 because they are not a journal, patent, or publication, and thus "not proper references for [an] Information Disclosure Statement."

Applicants respectfully disagree. The function of an Information Disclosure Statement is to bring to the attention of the Examiner "information" known to an individual associated with the patent application to be material to patentability (37 C.F.R. § 1.56 (a)). Contrary to the Examiner's position, there is no requirement for the "information" to be in a particular form. Further, 37 C.F.R. § 1.56 (a)(1) encourages Applicants to carefully examine "prior art cited in search reports of a foreign patent office," which is the situation here. Applicants respectfully request consideration of these references and indication of that consideration by initializing the PTO Form 1449 submitted April 18, 1997.

II. Rejections under 35 U.S.C. § 112, first paragraph

A. Written Description (SEQ ID NO:1 and SEQ ID NO:2)

At page 2, item 7, of Paper No. 17, the Examiner rejects claims 21-35 under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." In short, the Examiner objects to entry of the *corrected* nucleotide and amino acid sequences (SEQ ID NOS:1 and 2), which had been submitted to the PTO on May 28, 1997. Applicants' position was that the ATCC deposited clone 75899 inherently contained the correct sequence. The Examiner contends that the newly submitted SEQ ID NOS:1 and 2 are not supported in the specification. The Examiner requests that Applicants submit a declaration establishing the "chain of custody " indicating, for example, how the error arose, how the error was detected, and how one of ordinary skill in the

art could use routine experimentation to recognize and determine the correct sequence from the deposited material (Paper No. 17 at page 3). Applicants respectfully traverse this rejection, and reiterate and herein incorporate by reference the arguments made in the response filed May 28, 1997. Despite the sequence errors discussed in the Amendment filed May 28, 1997, Applicants submit that the captioned application provides an adequate written description of the subject matter encompassed by pending claims 21-29 and 31-34.

Claims 21-29 and 31-34 are directed to isolated polynucleotides, and to recombinant vectors and recombinant host cells comprising such isolated polynucleotides. In other words, these claims are directed to or ultimately dependent on a chemical compound and not to a nucleotide sequence. The nucleotide sequence is but an inherent property of the claimed polynucleotides.

There is a line of chemical case law where Applicants have been permitted to amend the specification to correct the formula of a chemical compound after an application's filing date provided that it had been demonstrated that one of skill in the art would have appreciated that the applicants were in possession of the compound itself at the time of filing. The rationale is that the formula is an inherent property of the compound and thus amending the specification to correct the formula is not new matter. *See, In re Nathan*, 140 U.S.P.Q. 601, 604 (C.C.P.A. 1964). *Accord Kennecott Corp. v. Kyocera Int'l, Inc.*, 5 U.S.P.Q.2d 1194, 1198 (Fed. Cir. 1987), *cert denied*, 486 U.S. 1008 (1988) ("The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of the earlier filing date").

In the field of biotechnology, Applicants often rely on a deposited clone, where the deposit was made prior to filing, to establish possession of claimed nucleic acids or proteins. The focus for determining whether Applicants were in possession of these nucleic acids or proteins has been

determined, at least in part, by considering whether the Applicant has (1) established that one skilled in the art in possession of the deposited clone would have been aware of both the DNA sequence and the encoded amino acid sequence, or would be able to determine these sequences without undue experimentation, (2) established that the DNA and amino acid sequences are described in a manner such that one skilled in the art could distinguish them from other sequences, and (3) resequenced a clone which is identical to that of the deposit and established a "chain of custody" for this clone. *See, e.g., Ex parte Maizel*, 27 U.S.P.Q.2d 1662, 1669-1670 (B.P.A.I. 1992).

Solely to expedite prosecution, Applicants submit herein an executed Declaration of John M. Greene and Robert D. Fleischmann setting forth the required facts so as to demonstrate that the Applicants were at all times in possession of the invention defined in claims 21-29 and 31-34.

At paragraph 10 of the attached Declaration of Greene and Fleischmann Under 37 C.F.R. § 1.132 [hereafter "Greene and Fleischmann Declaration"], Greene and Fleischmann state that they are of the opinion that the correct TNF receptor nucleotide and amino acid sequences would have been apparent to one skilled in the art in possession of ATCC Deposit No. 75899 and the data from the second sequencing run as of the March 15, 1995 filing date of the PCT/US 95/03216 application. Greene and Fleischmann base their position on the facts that the correct TNF receptor coding sequence can be readily determined from the deposited clone and that methods for sequencing this clone were routine in the art in March of 1995 (Greene and Fleischmann Declaration, ¶10). Thus, the nucleotide sequence of this clone is a chemical structure which is an inherent property of the clone. Further, this nucleotide sequence was in the possession of the inventors at the time the captioned application was filed. Furthermore, the TNF

receptor was described in the captioned application in sufficient detail so that one skilled in the art could distinguish the claimed invention from other receptors.

Applicants resequenced the cDNA clone HSABH13 containing nucleotide sequences that encode the TNF receptor *corrected* amino acid sequence of SEQ ID NO:2 of the present application (Greene and Fleischmann Declaration, ¶5). Applicants have also submitted evidence to establish that this clone is identical to that deposited at the ATCC and given Accession No. 75899 (See Greene and Fleischmann Declaration, ¶¶3 and 4). Applicants have thus established a "chain of custody" which demonstrates that the *corrected* nucleotide sequence data included in SEQ ID NO:1 of the present application was obtained from the HSABH13 cDNA clone deposited with the ATCC and given Accession No. 75899.

In view of the Greene and Fleischmann Declaration, the Examiner's rejection of claims 21-29 and 31-34 under 35 U.S.C. § 112, first paragraph is overcome and withdrawal of this rejection is respectfully requested.

B. *Enablement (Claim Scope)*

At page 3, item 8, of Paper No. 17, the Examiner rejects claims 30 and 35 under 35 U.S.C. § 112, first paragraph. The Examiner contends that while the specification is enabling for the disclosed nucleic acids comprising the sequence encoding SEQ ID NO:2, and allelic variants, it is the Examiner's position that the specification allegedly does not reasonably provide the full scope of enablement for the whole genus of variants or fragments of polynucleotides encoding SEQ ID NO:2.

The Examiner's rationale for this rejection is set forth on pages 3-5 of Paper No. 17. Applicants respectfully traverse this rejection. However, solely to expedite prosecution, claims 30 and 35 have been canceled. Accordingly, Applicants believe this rejection is moot and should be withdrawn.

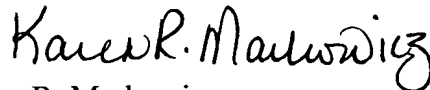
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned directly at (202) 371-2637.

Prompt and favorable consideration of this Response is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Karen R. Markowicz
Agent for Applicants
Registration No. 36,351

Date: March 13, 1998

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005
(202) 371-2600